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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/829,031	04/09/2001	Jeffrey Browning	A063 US	1334

7590 04/21/2003

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EXAMINER
LI, BAO Q

ART UNIT	PAPER NUMBER
1648	16

DATE MAILED: 04/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/829,031	BROWNING ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *6* is/are withdrawn from consideration.

5)☒ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7-8 and 9-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The copied of IDS originally filed on April 12, 2002 has been acknowledged.

Response to Amendment

This is a response to the amendment, paper No. 14, filed 03/03/03. Claims 1, 3, 4, 5, 7 and 8 have been amended. New claims 9-17 have been added. Claims 1-17 are pending before the examiner.

Claims 1-5, and 7-17 are considered before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-5, 7-8 and 9-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 1-2, 4-5, 7-8 and 9-14 are still rejected on the same ground as stated in the previous Office Action as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

4. Applicants traverse and submit that claim 1 has been amended; therefore the rejection should be withdrawn.

5. Applicants' argument has been respectfully considered; however, it is not found persuasive because the steps, such as the dosage, the route of the administration and schedule of the treatment are still missing in the claims. The claimed invention is a method of treating a disease using a special agent, which is not a popular medication that is used in routin; therefore, precise dosage and routs of administrating the said agent are required. This affects the dependent claims 3.

Claim Rejections - 35 USC § 112

6. Claims 1-5 and 7-14 are still rejected under 35 U.S.C. 112, first paragraph on the same ground as stated in the previous Office Action, because the specification, while being enabling for reducing the symptom caused by the infection of lymphocytic choriomengitis virus clone 13 (LCMV-13) in a mouse model with lymphotoxin-β (LT-β) or lymphotoxin-beta-receptor-Ig fusion protein (LTβR-Ig), or plus an antibody against TNF-α, TN3-19.12 or use of monoclonal antibody BD8 mAb, does not reasonably provide enablement for having a method of using LT-β or LTβR-Ig for inducing an anti-viral response in human for other viruses, such as Sin Nombre virus (SNV), Ebola virus, Marburg virus Lassa virus and Dengue virus. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

7. Applicants argue that LCMV-infected mice is an accepted model for studying of virus-induced systemic shock and respiratory distress, including, but not limited to SNV. Thus, Applicants assert that examples of LT-β and LT-βR blocking agents and the LCMV model system taught in the specification should not be used to limit the claimed invention.

8. Applicants argument has been respectfully considered; however, it is not found persuasive because Applicants do not provide the literature support of Applicants' assertion that LCMV-infected mice is an accepted model for studying of virus-induced systemic shock and respiratory distress. Examiner has conducted literature search in the art regarding the animal model of viral-induced systemic shock and respiratory distress and has not found any document indicating that LCMV-infected mice is an accepted model for studying of virus-induced systemic shock and respiratory distress. Applicants are encouraged to provide any evidence to support this argument.

9. Applicants further argue that LCMV is recognized model for studding viral-induced reaction, including those induced by SNV, SNV is a member of the Bunyviridae genus and LCMV is a member of the Old World Arenaviridae genus and they share common mechanism. Lassa virus is classified in the same genus as LCMV. Therefore, the claimed invention should be enabled in view of the example taught in the specification.

10. Applicants' argument has been fully considered; however, it is not found persuasive because LCMV does not belong to the same genus of all claimed human viruses, such as Ebola virus, Marburg virus and Dengue virus. Further, Field et al. does not teach LCMV is recognized as a model for studding other family viral-induced response.

11. Moreover, Applicants have not answered the question raised in the previous Office Action that is whether systemic shock induced by Sin Nombre virus (SNV), Ebola virus and Dengue virus are through the same mechanism. Because Sin Nombre virus (SNV), Ebola virus and Dengue virus are structurally different viruses, similar clinical symptoms appeared in different viral infections could be induced by totally different mechanisms as discussed in the previous Office Action.

12. Therefore, considering the broad scope of the claimed invention, the rejection is still maintained.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

14. Claims 1-5 and 12-14 are still rejected under 35 U.S.C. 102(a) as being anticipated by Browning et al. (WO 98/17313A2) on the same ground as stated in the previous Office Action.

15. Applicants traverse the rejection and submit that reference "313" does not teach or suggest Applicants claimed invention because Reference " 313" describes the use of LT blocking agents as a priming agent to be used in combination with other antiviral agents, and does not describe the use of LT blocking agents for treating viruses directly.

16. Applicants' argument has been respectfully considered; however, it is not persuasive because Reference "313" does not teach the use of the LT blocking agent must be in combination with other anti-viral agent. For example, in example 4 of page 61 and example 7 on pages 72-63, the experimental animals were treated with LTβ-R-Ig along. Furthermore, the use of LT

blocking agents in combination with other antiviral agents does not mean that it is not used for treating virus directly and the limitation of using LT blacking agent directly and not in combination with other antiviral agent argue is not cited in the claims.

17. Applicants further argue that Applicants have shown that LT blocking agents are effective in directly blocking severe host response to aggressive virus, especially for the patients with systemic shock and/or pulmonary distress. Whereas, the HIV infection described in reference "313" is not associated with systemic shock and/or pulmonary distress as required by the pending claims. Accordingly, Applicants respectfully request to withdrawn the rejection.

18. Applicants' argument has been fully considered; however, it is not found persuasive because the claimed invention does not directed to the treatment of viral induced systematic shock, it is directed to the treatment of viral infection.

19. Regarding to the claims 15-17, the specification does not teach the TL blocking agent is able to treat the viral-induced pulmonary distress.

20. Therefore, the claimed invention is still anticipated by the cited reference. The rejection is maintained.

21.

Conclusion

22. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li
April 16, 2003

JAMES HOUSEL 4/21/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600